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EXAMINER	
MATTISON, LORI K	
ART UNIT	**PAPER NUMBER**
4161	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,346	COX ET AL.	
	Examiner	Art Unit	
	LORI K. MATTISON	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *3/10/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *55-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/31/2006; 4/15/2005; 1/29/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-54 are currently pending. Claims 55-59 were withdrawn by applicant in an amendment dated March 10, 2008. Claims 1-54 are under examination as the elected invention. This is the first Office Action on the merits of the claims.

Information Disclosure Statement

The examiner notes that U.S. Publication No. 2001/0002272, U.S. Patent No. 5,000,943, U.S. Publication No. 2002/0110224 and U.S. Patent No. 5,011,679 were kindly supplied by applicants in an IDS statement filed on 1/29/04.

The examiner notes that US Publication No. 2002/0043941 is drawn to colored EL display. US Patent No. 6,227,420 is drawn to a drawback valve. These references can be found listed in the IDS statement filed on 1/29/04/.

Election/Restrictions

Applicant's election without traverse of Invention I, claims 1-54, in the reply filed on 3/10/2008 is acknowledged. The restriction requirement is deemed proper and is therefore made FINAL.

Inventorship

In view of the papers filed 8/9/2004, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the

inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by Lori Mattison Ph.D.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 101

Claims 1-11, 14, 15, and 16-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The edible composition, as claimed, has the same characteristics as those found naturally, for example in blackberries, which contain at least zinc and manganese (and which may be consumed by pet birds to meet their caloric and nutritional requirements, thus acting like an oral medicament against malnutrition), and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that claims 1 and 16 be amended by inserting the terminology that would distinguish the claimed edible composition from those that may exist naturally.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "adapted" in claim 1 is a term which renders the claim indefinite. The term "adapted" is indefinite. In the instant case, it is unclear as to what "adapted" means.

Claims 2-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "at least about " in claims 2, 4, and 5 is a term which renders the claim indefinite. The term "at least" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case is it is unclear as to what "at least about" means.The examiner has interpreted these claims broadly.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 15 is a term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case is it is unclear whether "substantially free" means "lacking", "containing," or "having a little bit of". The examiner has interpreted these claims broadly.

Claims 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "at least about " in claims 17, 19, 20, and 23 is a term which renders the claim indefinite. The term "at least about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case is it is unclear as to what "at least about" means. The examiner has interpreted these claims broadly.

Claims 27-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 27 is a term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case is it is

unclear whether "substantially free" means "lacking", "containing," or "having a little bit of". The examiner has interpreted these claims broadly.

Claims 29-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "at least about" in claims 29, 31, 35, and 36 is a term which renders the claim indefinite. The term "at least about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case is it is unclear as to what "at least about" means. The examiner has interpreted these claims broadly.

Claims 38-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 38 is a term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case is it is unclear whether "substantially free" means "lacking", "containing," or "having a little bit of". The examiner has interpreted these claims broadly.

Claims 39-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "at least about " in claims 39, 42, 46, and 47 is a term which renders the claim indefinite. The term "at least about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case is it is unclear as to what "at least about" means. The examiner has interpreted these claims broadly.

Claims 49-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 38 is a term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case is it is unclear whether "substantially free" means "lacking", "containing," or "having a little bit of". The examiner has interpreted these claims broadly.

Claims 50-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "at least about " in claims 50, and 54 is a term which renders the claim indefinite. The term "at least about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case

is it is unclear as to what "at least about" means.The examiner has interpreted these claims broadly.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 rejected under 35 U.S.C. 102(b) as being unpatentable by U.S. Patent No. 6,159,530 (hereinafter '530) by Christiansen.

Instant claim 1 recites an edible composition comprising an amount of a soluble mineral component, wherein the soluble mineral component comprises two or more minerals selected from the group consisting of zinc, manganese, .tin, copper, and mixtures thereof, wherein the amount is an effective amount for use as an oral medicament, and wherein the edible composition is adapted for use by a companion animal.

The examiner had given no patentable weight to the whereby clause " "wherein the edible composition is adapted for use by a companion animal, " other than the dog could eat the edible composition. The examiner's rationale for doing so is that the whereby clauses of the instant claim provide intended use for the composition. The MPEP states that "If a prior art structure is capable of performing the intended use as

recited in the preamble, then it meets the claim." See, e.g., *In re* Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed.Cir. 1997)

The '530 prior art teaches an edible composition, a processed cereal (Abstract). The process cereal may be fortified by coating the processed cereal piece with the metal amino acid chelate(s)(Abstract). The metal amino acid chelate is specifically taught to include the minerals magnesium, zinc, copper, and manganese. (Col. 7, lines 15-18). These minerals are soluble because the metal amino acid chelate is taught to form a solution. "First, the metal amino acid chelate should be dry blended with a sugar or dextrose to form a blend. Next, the blend is mixed with water until a homogenous solution is formed. The aqueous chelate solution is then sprayed onto the pieces until adequately coated followed by a drying step." (Col. 8, lines 9-13). Coating of the processed cereal pieces with the mineral/metal chelate is also taught (Col. 5; lines 17-22; Col. 8, lines 9-13; Example 1, Col 8, line 49; Example 2, Col 8, line 67) . The '530 prior art also teaches having more than two or more minerals present in the edible composition. Specifically, "one or more metal amino acid chelates may be combined by either ….. 2) coating the processed cereal piece with the metal amino acid chelate(s)." (Abstract). The examiner notes that fortification of food stuffs is performed to enrich the nutrient composition of foods and prevent malnutrition.

Instant claim 2 recites the limitations of instant claim 1 with the additional limitations that a) when the composition comprises zinc, the composition comprises at least about 0.001% zinc ion, by weight of the composition; b) when the composition comprises tin, the composition comprises at least about 0.0001% tin ion; by weight of the

composition; c) when the composition comprises copper, the composition comprises at least about 0.0005% copper ion, by weight of the composition; and d. when the composition comprises manganese, the composition comprises at least about 0.0001% manganese ion, by weight of the composition.

The limitations of instant claim 1 is addressed supra.

The '530 prior art teaches that "depending on what metal is used to fortify the various processed cereal pieces, the metal should be present in or on the various pieces from about 0.001% to 2% by weight. (Col. 7, lines 17-20)." "For example, …zinc and iron will be present closer to the lower limit of this range, i.e., from about 0.001% to 0.1% by weight. "(Col. 7, lines 21-24). Therefore, one of ordinary skill in the art would envisage zinc, copper, and manganese are present in an amount at least about 0.001%, 0.0005%, and 0.0001%, respectively.

Instant claim 3 recites the limitations of instant claim 2, which depends from instant claim 1, with the additional limitation that at least a portion of the mineral component is coated on the surface of the composition.

The limitations of instant claims 1 and 2 are addressed supra.

The '530 prior art teaches spraying the mineral component (i.e. the metal aminoacid chelate) on to the processed cereal. Therefore, at least a portion of the mineral component is coated on the processed cereal (Abstract, Col. 5; lines 17-22; Col. 8, lines 9-13; Example 1, Col 8, line 49; Example 2, Col 8, line 67).

Instant claim 4 recites the limitaitons of instant claim 3, which depends from instant claim 2 which depends from instant claim 1, with the additional limitation that at least about 50% of the mineral component, by weight of the mineral component, is coated on the surface of the composition.

The limitations of instant claims 1-3 are addressed supra.

The mineral containing component, i.e. the metal amino acid chelate, is taught to be sprayed topically onto the surface of the processed cereal (Abstract, Col. 5; lines 17-22; Col. 8, lines 9-13; Example 1, Col 8, line 49; Example 2, Col 8, line 67). Therefore, 100% of the mineral containing component is topically on the processed cereal.

Claims 1 is rejected under 35 U.S.C. 102(b) as being unpatentable over U.S. Patent No. 6,277,435 (hereinafter '435) by Lacombe *et al.*

The '435 prior art recites an edible composition (abstract). This composition may contain the soluble mineral components copper sulfate, and manganese sulfate (Col.4, lines 3-10). A stated advantage of the food is "to provide a pet food which can be served daily, with noticeable improvement in the animal's health" (Col.3, lines 1-3) demonstrating that it is an oral medicament for noticeably improving the animals health.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,277,435 (hereinafter '435) by Lacombe *et al* and The Merck Veterinary Manual 8th Edition as copyrighted in 1998.

Instant claim 2 recites the limitations of instant claim 1 with the additional limitations that a. when the composition comprises zinc, the composition comprises at least about 0.001% zinc ion, by weight of the composition; b. when the composition comprises tin, the composition comprises at least about 0.0001% tin ion; by weight of the composition; c. when the composition comprises copper, the composition comprises at least about 0.0005% copper ion, by weight of the composition; and d. when the composition comprises manganese, the composition comprises at least about 0.0001% manganese ion, by weight of the composition.

The limitations of instant claim 1 are addressed supra.

The '435 prior art teaches an edible composition (abstract). This composition teaches inclusion of the soluble mineral components copper sulfate, and manganese

sulfate (Col.4, lines 3-10). The '435 prior art also teaches that the pet food composition is to be served daily (Col. 3, lines 1-2).

The '435 prior art does not teach the concentration of copper, zinc, or tin ions (when present) to be included in the food.

The Merck Veterinary Manual 8th Edition teaches the American Association of Feed Control (AAFCO) Nutrient Requirements for dogs. In particular, the minimum amount of Manganese required in dog food is 5 mg/kg, (or 0.0005% by weight). The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight).

Therefore, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to optimize the amount of copper sulfate and manganese sulphate in the pet food composition of the '435 prior art to provide a composition which contains at least 0.0001% manganese ion and 0.0005% copper ion. One of ordinary skill in the art would have been motivated to do so because the Merck Veterinary Manual teaches that dog foods require copper and manganese ions to be present in an amount that is 0.00073% and 0.0005% by weight, respectively.

Instant claim 5 recites the limitations of instant claim 2, which depends from instant claim 1, with the additional limitation that the edible composition comprises least about 0.02% of the mineral component, by weight of the composition.

The limitations of instant claims 1 and 2 are addressed supra.

The '435 prior art teaches a pet food composition. This composition is may contain the copper sulfate and manganese sulfate which are soluble mineral components (Col.4, lines 3-10).

The '435 prior art does not teach that the soluble mineral component comprise of 0.02% of the pet food composition by weight.

The Merck Veterinary Manual 8th Edition teaches the American Association of Feed Control (AAFCO) Nutrient Requirements for dogs. In particular, the minimum amount of Manganese required in dog food is 5 mg/kg, (or 0.0005% by weight). The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight) while the maximum amount of copper permitted is 250 mg/kg (0.025% by weight). Hence, the range of the mineral soluble component of the pet food composition taught by the '435 prior art range from 0.00123- 0.02573% by weight.

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to optimize the mineral soluble component of the pet food composition taught '435 prior art to have a mineral soluble component that is 0.02% by weight. One of ordinary skill in the art would have been motivated to do so because the Merck Veterinary Manual teaches the desired range for the metal ions which may comprising the soluble mineral component and to select 0.02% for the soluble mineral component would have been a matter of routine optimization within a previously taught range.

Instant claim 6 recites the limitations of instant claim 5, which depends from instant claim 2 which depends from instant claim 1, with the additional limitation that (a) when the mineral component comprises zinc, the mineral component comprises a salt selected from the group consisting of zinc sulfate, zinc gluconate, zinc chloride, zinc citrate, zinc lactate, zinc malate, and mixtures thereof; (b) when the mineral component

comprises tin, the mineral component comprises a salt selected from the group consisting of tin lactate, tin gluconate, tin acetate, tin sulfate, tin malate, and mixtures thereof; (c) when the mineral component comprises copper, the mineral component comprises a salt selected from the group consisting of copper chloride, copper gluconate, copper sulfate, copper bisglycinate, copper lactate, copper malate, copper acetate, and mixtures thereof; and (d) when the mineral component comprises manganese, the mineral component comprises a salt selected from the group consisting of manganese chloride, manganese sulfate, manganese gluconate, manganese acetate, and mixtures thereof.

The limitations of instant claims 1, 2, and 5 are addressed supra.

The '435 prior art teaches inclusion of the soluble mineral components copper sulfate, and manganese sulfate (Col.4, lines 3-10).

Instant claim 7 recites the limitations of instant claim 6, which depends from instant claim 5 which depends from instant claim 2 which depends from instant claim 1, with the additional limitation that: (a) when the composition comprises zinc, the composition comprises from about 0.001% to about 1% zinc ion, by weight of the composition; (b) when the composition comprises tin, the composition comprises from about 0.0005% to about 0.1% tin ion, by weight of the composition; (c) when the composition comprises copper, the composition comprises from about 0.0005% to about 0.1% copper ion, by weight of the composition; and (d) when the composition comprises manganese, the composition comprises from about 0.001% to about 0.5% manganese ion, by weight of the composition.

The limitations of instant claims 1, 2, 5, and 6 are addressed supra.

The '435 prior art teaches a pet food composition teaches which includes the soluble mineral components copper sulfate, and manganese sulfate (Col.4, lines 3-10).

The '435 prior art does not teach the percentage of copper sulfate, and manganese sulfate (by weight) in the pet food composition to yield the recited percentage for copper and manganese ions.

The Merck Veterinary Manual 8th Edition teaches the American Association of Feed Control (AAFCO) Nutrient Requirements for dogs. In particular, the minimum amount of Manganese required in dog food is 5 mg/kg, (or 0.0005% by weight). The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight). The maximum amount of copper required in dog food is 250 mg/kg (0.025% by weight).

Therefore, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to optimize the amount of copper sulfate and manganese sulfate in the pet food composition of the '435 prior art to create a pet food composition which contains at least 0.001% to about 0.5% manganese ion (by weight) and about 0.0005% to about 0.1% copper ion (by weight). One of ordinary skill in the art would have been motivated to do so because the Merck Veterinary Manual teaches the recited values for the said ions; selection of recited values is an optimization of a previously taught range.

Instant claims 8-12 and 14, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,277,435 (hereinafter '435) by Lacombe *et al* and The Merck Veterinary Manual 8th Edition as copyrighted in 1998, as applied to instant claims

1,2, 5-7 above, in further view of U.S. Patent 5,000,943 (hereinafter '943) by Scaglione *et al.*

Instant claim 8 recites the limitations of instant claim 7, which depends from instant claim 6 which depends from instant claim 5 which depends from instant claim 2 which depends from instant claim 1, with the additional limitation that the composition comprises a phosphate component, wherein the further amount is an effective amount for use as an oral medicament.

The limitations of instant claims 1,2, and 5-7 are addressed supra.

The '435 prior art teaches a pet food composition teaches that includes the soluble mineral components copper sulfate, and manganese sulfate (Col.4, lines 3-10). An advantage or objective of the pet food composition is to have a noticeable improvement in pet health (Col. 3, lines 1-4). The pet food composition may be wet or dehydrated (Col. 3, lines 12-14). The Merck Veterinary Manual 8th Edition teaches the percentage of copper and manganese ions present (by weight) in dog food compositions.

However, the '435 prior art and the Merck Veterinary Manual 8th Edition do not teach inclusion of phosphate.

The '943 teaches a canine biscuits which contain an inorganic pyrophosphate (title). The '943 prior art teaches that the inorganic pyrophosphate contained in the dog biscuit reduces or prevents tartar on the dog's teeth (abstract). The pyrophosphates are also taught to be anti-tartar, anti-plaque or anti-calculus agents (Col.8, lines 27-30). The '943 prior art teaches that pyrophosphates should be included in the biscuit in amount such that pyrophosphates comprise of 0.1 to 5 weight percent of the total composition (Col. 11; lines 16-20). The '943 prior art provides data from other patents which suggest

that the disclosed concentrations are effective in reduced tartar accumulations (Col. 11, lines 22 -33), demonstrating that an amount of 0.1 to 5 weight percent is an effective amount as an oral medicament.

Therefore, it would have been prima facie obvious to anyone of ordinary skill in the art at the time the invention was made to included phosphate (specifically pyrophosphates) in the pet food composition taught by the '435 prior art. One of ordinary skill would have been motivated to do so because objective of the '435 prior art is to provide a noticeable improvement in pet health and the '943 prior art teaches that pyrophosphates are anti-tartar, anti-plaque or anti-calculus agents.

Instant claim 9 recites the limitations of instant claim 8, which depends from instant claim 7 which depends from instant claim 6 which depends from instant claim 5 which depends from instant claim 2 which depends from instant claim 1, wherein at least a portion of the phosphate component is a pyrophosphate.

The limitations of instant claims 1,2, and 5-8 are addressed supra.

The '943 prior art teaches inclusion of pyrophosphate (abstract, Col.8, lines 27-30; Col. 11; lines 16-20).

Instant claim 10 recites the limitations of instant claim 8, which depends from instant claim 7 which depends from instant claim 6 which depends from instant claim 5 which depends from instant claim 2 which depends from instant claim 1, with the additional limitation that at least a portion of the phosphate component is a polyphosphate.

The limitations of instant claims 1,2, and 5-8 are addressed supra.

The '943 prior art teaches inclusion of pyrophosphate (abstract, Col.8, lines 27-30; Col. 11; lines 16-20). The examiner notes that pyrophosphate is a polyphosphate.

The '943 prior art also teaches inclusion of other polyphosphates beyond pyrophosphate (Col. 10, lines 50-54)

Instant claim 11 recites the limitations of instant claim 8, which depends from instant claim 7 which depends from instant claim 6 which depends from instant claim 5 which depends from instant claim 2 which depends from instant claim 1, with the additional limitation that the edible composition comprises three or more minerals selected from the group consisting of zinc, manganese, tin, copper, and mixtures thereof.

The limitations of instant claims 1,2, and 5-8 are addressed supra.

As discussed above, the '435 prior art teaches the minerals manganese and copper (Col.4, lines 3-10), which are soluble. The '435 prior art also teaches inclusion of zinc, in the form of zinc oxide (Col.4, lines 3-10).

Instant claim 12 recites the limitations of instant claim 8, which depends from instant claim 7 which depends from instant claim 6 which depends from instant claim 5 which depends from instant claim 2 which depends from instant claim 1, with the additional limitation that the composition is a companion animal biscuit.

The '435 prior art teaches that the pet food composition contains a combination of proteinaceous and farinaceous ingredients (Col. 2, lines 33-37). The '435 prior art teaches that the food composition can be dehydrated (Col. 3, lines 11-15), which the

examiner notes would give it a crunchy, cookie type texture due to inclusion of the farinaceous ingredients. The '435 prior art also notes that, " it will be apparent to those of ordinary skill in the art that many modifications or substitutions with comparable components may be made to the pet food and the method of making the food which are suggested by the present invention and considered to be within the scope of the present invention (Col. 4, lines 29-34).

The '435 prior art does not teach that the pet food composition can be formed into a biscuit.

The '943 prior art teaches a canine biscuit (Abstract). This biscuit also contains proteinaceous and farinaceous ingredients (Col. 14, Table 1; Col. 7, lines 50-54). The '943 prior art teaches that the biscuits clean tooth surfaces, exercises, and massages the gums (Col. 8, lines 40-44). The '943 prior art teaches that Milk Bone dog biscuits have been a commercial success for many years (Col. 13, lines 33-35)

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art, at the time the invention was made, to modify the dehydrated pet food composition taught by the '435 prior art to form an animal biscuit. One would have been motivated to do so because the objective of the '435 prior art is to improve overall health of the animal. The '943 prior art teaches that dog biscuits clean tooth surfaces, exercises and massages the gums of the animal, providing a stimulus for modification of the composition of the '435 prior art. One of ordinary skill in the art would have been also further motivated to modify the pet food composition taught by the '435 prior art to form a biscuit because the '943 prior teaches that dog biscuits are commercially successful.

Instant claim 14 recites the limitations of instant claim 8, which depends from instant claim 7 which depends from instant claim 6 which depends from instant claim 5 which depends from instant claim 2 which depends from instant claim 1, with the additional limitation that the edible composition is a companion animal food.

The limitations of instant claims 1,2, and 5-8 are addressed supra.

The composition of the '435 prior art teaches a pet food composition, which is an animal food. (Col. 1, lines 9-11).

Instant claim 15 recites the limitations of instant claim 8, which depends from instant claim 7 which depends from instant claim 6 which depends from instant claim 5 which depends from instant claim 2 which depends from instant claim 1, with the additional limitation that the edible composition is substantially free of rawhide.

The limitations of instant claims 1,2, and 5-8 are addressed supra.

The '435 prior art teaches that the pet food composition is substantially free of rawhide. In particular, inclusion of rawhide is not specificially disclosed.

Instant claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,277,435 (hereinafter '435) by Lacombe *et al* and The Merck Veterinary Manual 8th Edition as copyrighted in 1998, and U.S. Patent 5,000,943 (hereinafter '943) by Scaglione *et al*, as applied to instant claims 1, 2, and 5-8 above, in further view of WO 01/17364 (hereinafter '364) by Hodge *et al*.

Instant claim 13 recites the limitations of instant claim 8, which depends from instant claim 7 which depends from instant claim 6 which depends from instant claim 5 which depends from instant claim 2 which depends from instant claim 1, with the additional limitation that the edible composition is an animal chew.

The limitations of instant claims 1,2, and 5-8 are addressed supra

The '435 prior art teaches that the pet food composition contains a combination of proteinaceous and farinaceous ingredients (Col. 2, lines 33-37). The '435 prior art teaches that the food composition can be dehydrated (Col. 3, lines 11-15). The '435 prior art also notes that, " it will be apparent to those of ordinary skill in the art that many modifications or substitutions with comparable components may be made to the pet food and the method of making the food which are suggested by the present invention and considered to be within the scope of the present invention (Col. 4, lines 29-34).

The '435 prior art does not teach that the pet food composition can be formed into a chew.

The '364 prior art teaches a meaty chew which also contains proteinaceous and farinaceous ingredients (page 11; lines 14-16). The '364 prior art teaches that the water content of the finished product will largely depend on whether the product is a "dry," biscuit-style treat or a "meaty chew" bar or a bit food product (page 11, lines 7-8).

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to optimize the farinaceous ingredients and dehydration parameters used to make the pet food composition of the '435 prior art. One would have been motivated to do so because the '364 prior art teaches that water content present in a

product determines whether it is a dry biscuit or a meaty chew. The examiner notes that the pet food composition of the '435 prior art is dehydrated, optimization of the dehydration time would likely yield "meaty," chew with a texture similar to that of jerky consumed by humans which is also made through dehydration.

Instant claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,247,562 (hereinafter '562) by Bernotavicz and U.S. Publication No. 2001/0002272 (hereinafter the '272) by Brunner, U.S. Patent No. 2,859,115 (hereinafter the '115) by Rivoche and U.S. Patent No. 5,171,603 (hereinafter the '603) by Singer *et al.*

The examiner had given no patentable weight to the whereby clauses "wherein the amount is an effective amount for use as an oral medicament", and "wherein the further amount is an effective amount for use as an oral medicament." The examiner's rationale for doing so is that as these whereby clauses provide intended use for the composition. The MPEP states that "If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim." See, e.g., *In re* Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed.Cir. 1997)

Instant claim 16 recites an edible composition comprising: (a) an amount of a soluble mineral component, wherein the soluble mineral component comprises one or more minerals selected from the group consisting of zinc, manganese, tin, copper, and mixtures thereof; wherein the amount is an effective amount for use as an oral medicament; and (b) a further amount of a phosphate component, wherein the further

amount is an effective amount for use as an oral medicament; wherein the edible composition is selected from the group consisting of companion animal foods companion animal supplements, and combinations thereof, wherein the companion animal supplement is not a chew.

The '562 prior art discloses a moist pet food with blood chunks and a fluid gravy system. This composition is composed of chunks made from blood and flavorful, nutritional vitamin and mineral fortified gravy (Col.4, lines 9-11). The liquid gravy is fortified with the minerals calcium, phosphorous, potassium, sodium chloride, magnesium, iron, copper, manganese, zinc, iodine and selenium (Col. 5, lines 37-40). The '562 prior art teaches that other flavoring agents can be any suitable ingredients or mixtures thereof which imparts the desired flavor to a gravy to help round out and balance the aroma and taste of the such material (Col. 4 lines 47-50). The '562 prior art also teaches inclusions of milk solids, sugar, salt and emulsifiers, which aid in accentuating the flavor and appeal of dry pet food or other pet food. (Col. 5, lines 45-48)

However, the '562 prior art does not teach inclusion of phosphate.

The '272 prior art teaches that tetrasodium pyrophosphate is an agent which enhances the palatability or taste of a composition (paragraph 10, 17, Examples 1-6; R_2 and R_3). The '272 prior art teaches that the palatability enhancer may be used in dog food (Col. Lines) which may be dry or semi-moist.

However, the '272 prior art does not teach that the tetrasodium pyrophosphate may be used in "wet" compositions.

The '115 prior art (Example 8; Col. 7 and 8) teaches that tetrasodium pyrophosphate is an emulsifying agents used with wet compositions (i.e. canned tomato

soup and water). The '603 art teaches that tetrasodium pyrophosphate is an emulsifying agent (Col. 8, lines 60-68)

Therefore, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to include tetrasodium pyrophosphate in the composition taught by the '562 prior art. One would have been motivated to do so because the objective the '562 prior art is to provide that compostion that is flavorful and nutritionally fortified (Col.4, lines 9-11) while accentuating the flavor and appeal of dry pet food or other pet food. (Col. 5, lines 45-48). The '272 prior art teaches that tetrasodium pyrophosphate improves the taste of animal food and encourages increased consumption (Examples 1-6) of pet food. The '115 prior art teaches that tetrasodium pyrophosphate is an emulsifying agent; the '562 prior art teaches inclusion of emulsifiers to aid in accentuating the flavor and appeal of dry pet food or other pet food. (Col. 5, lines 45-48)

Instant claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,247,562 (hereinafter '562) by Bernotavicz , U.S. Publication No. 2001/0002272 (hereinafter the '272) by Brunner, U.S. Patent No. 2,859,115 (hereinafter the '115) by Rivoche and U.S. Patent No. 5,171,603 (hereinafter the '603) by Singer *et al*, as applied to instant claim 16 above, in view of The Merck Veterinary Manual 8th Edition as copyrighted in 1998.

Instant claim 17 recites the limitations of instant claim 16 with the additional limitations that : (a) when the composition comprises zinc, the composition comprises at least about 0.001% zinc ion, by weight of the composition; (b) when the composition comprises tin, the composition comprises at least about 0.0001% tin ion, by weight of the composition; (c) when the composition comprises copper, the composition comprises at least about 0.0005% copper ion, by weight of the composition; and (d) when the composition comprises manganese, the composition comprises at least about 0.0001% manganese ion, by weight of the composition.

The limitations of instant claim 16 are addressed supra.

The '562 prior art teaches a moist pet food with blood chunks and a fluid gravy system. This composition is composed of chunks made from blood and flavorful, nutritional vitamin and mineral fortified gravy (Col.4, lines 9-11). The liquid gravy is fortified with the minerals calcium, phosphorous, potassium, sodium chloride, magnesium, iron, copper, manganese, zinc, iodine and selenium (Col. 5, lines 37-40). The '562 prior art teaches enriching composition to provide 25-100 percent of National Research Council's (NRC) requirements of vitamins or minerals (Col. 5, lines, 25-36, Examples II, III, and IV), demonstrating a desire to provide a nutritionally-sound composition.

The '562 prior art does not teach the percentages that manganese, copper, or zinc should be present in.

The Merck Veterinary Manual 8th Edition teaches the American Association of Feed Control (AAFCO) Nutrient Requirements for dogs. In particular, the minimum

amount of Manganese required in dog food is 5 mg/kg, (or 0.0005% by weight). The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight) while the maximum amount of copper permitted is 250 mg/kg (0.025% by weight). The minimum amount of zinc required is 0.012%.

Therefore, it would be *prima facie* obvious to modify amount of zinc, manganese, and copper present in mineral fortified gravy of the '562 prior art to the recited amounts. One of ordinary skill in the art would have been motivated to do so because the '562 prior art expresses a desire to provide a nutritionally-sound composition by following recommended guidelines for such compositions, while the Merck Index of Veterinary Manual teaches the nutrient requirements for dogs which fall within the recited mineral range.

Instant claim 18 recites the limitations of instant claim 17, which depends from instant claim 16, with the additional limitation that least a portion of the mineral component is coated on the surface of the composition.

The limitations of instant claims 16 and 17 are discussed supra.

The blood chunks are mixed with the mineral fortified gravy (Examples I, II, and III; Col. 7 and Col. 8). Therefore, a portion of the mineral mix is topically applied.

Instant claim 19 recites the limitations of instant claims 18, which depends from instant claim 17 which depends from instant claim 16, with the additional limitation that wherein at least about 50% of the mineral component, by weight of the mineral component, is coated on the surface of the composition.

The limitations of instant claims 16, 17, and 18 are discussed supra.

The '562 prior art teaches enriching the gravy of the composition to up to 100 percent of National Research Council's (NRC) requirements of vitamins or minerals (Col. 5, lines, 25-36, Examples II, III, and IV). Example II (Col. 8) discloses that the blood chunks make up 50 percent of the gravy by weight. The examiner notes that the remaining 50 % must be the gravy. The gravy component contains the minerals. Therefore, at least about 50% of the mineral component, by weight of the mineral component, must be coated on the surface of the blood chunks in absence of any evidence to the contrary.

Instant 20 recites the limitations of instant claim 19, which depends from instant claim 18 which depends from instant claim 17 which depends from instant claim 16, with the additional limitation that comprising at least about 0.02% of the mineral component, by weight of the composition.

The limitations of instant claims 16, 17, 18 and 19 are discussed supra.

The Merck Veterinary Manual 8th Edition teaches the American Association of Feed Control (AAFCO) Nutrient Requirements for dogs. In particular, the minimum amount of Manganese required in dog food is 5 mg/kg, (or 0.0005% by weight). The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight) while the maximum amount of copper permitted is 250 mg/kg (0.025% by weight). The minimum amount of zinc required is 0.012%. The maximum amount of zinc required is 0.1 %. Therefore the amount of the recited minerals can range from 0.01323-0.1255% (page 1626). The Merck Veterinary Manual also teaches that as intake of mineral exceeds the requirement an excessive amount may be absorbed or a large amount of the

unabsorbed mineral may prevent intestinal absorption of other minerals in adequate amounts. Manipulation of dietary intake of Ca, P Na, Mg (dogs and cats), and Cu for therapeutic effect is common (page 1630; Minerals section).

Therefore, it would be *prima facie* obvious to optimize the amount of zinc, manganese and copper in the composition recited by the '562 prior art. One would have been motivated to optimize the amount of the minerals within the known range because the Merck Veterinary Manual teaches that excessive amounts of minerals can be detrimental to the animal's health. Yet, manipulation of dietary intake of minerals for a therapeutic effect is common. The recited range is an optimization of a previously known parameter.

Instant claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,247,562 (hereinafter '562) by Bernotavicz , U.S. Publication No. 2001/0002272 (hereinafter the '272) by Brunner, , U.S. Patent No. 2,859,115 (hereinafter the '115) by Rivoche, U.S. Patent No. 5,171,603 (hereinafter the '603) by Singer *et al*, The Merck Veterinary Manual 8th Edition as copyrighted in 1998, as applied to instant claim 16 -20 above, in further view of U.S. Patent No. 6,277,435 (hereinafter '435) by Lacombe *et al*. and U.S. Patent No. 3,422,182, (hereinafter '182) by Knapp *et al*.

Instant claim 21 recites the limitations of instant claim 20, which depends which depends from instant claim 19 which depends from instant claim 18 which depends from

instant claim 17 which depends from instant claim 16, with the additional limitation that the zinc, tin, copper, and manganese, if present, are selected from Markrush groups.

The limitations of instant claims 16, 17, 18, 19 and 20 are discussed supra.

The '562 prior art teaches that the liquid gravy is fortified with the minerals calcium, phosphorous, potassium, sodium chloride, magnesium, iron, copper, manganese, zinc, iodine and selenium (Col. 5, lines 37-40). The '562 prior art teaches inclusion of water in the gravy (Examples II-V)

The '562 prior art does not teach the recited species from the Markrush groups for zinc, copper, or manganese.

The '435 prior art recites an edible composition (abstract) pet food composition. This composition may contain the soluble mineral components copper sulfate, and manganese sulfate (Col.4, lines 3-10). The examiner notes that these salts are water soluble. A stated advantage of the food is "to provide a pet food which can be served daily, with noticeable improvement in the animal's health" (Col.3, lines 1-3).

However, the '435 prior art does not teach inclusion of a zinc species that is recited by the Markush group.

The '182 prior art discloses that administration of zinc in the dog's diet is effective in the treatment of skin diseases such as demodectic mange and summer eczema. The zinc can be administered in the animal's drinking water or food (Col 2. lines 41-50). Zinc salts such as zinc sulfate, zinc chloride, zinc carbonate are specifically disclosed as being effective (Col. 2, lines 60-65). Zinc sulfate and zinc chloride are disclosed as being water soluble zinc salts (Col. 2, lines 60-65). The '182 prior art

teaches inclusion of copper sulfate when to prevent zinc induced anemia (Col. 3, lines 1-5), particularly when zinc sulfate is used (Col. 3, lines 5-14)

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to utilize copper sulfate, zinc chloride and/or zinc sulfate, and manganese sulfate in the gravy component of the dog food composition of the '562 prior art. One would have been motivated to do so because the '562 prior art teaches that copper, zinc and manganese ions are present in the gravy component. The gravy component contains water and zinc sulfate, zinc chloride, copper sulfate, and manganese sulfate are water soluble salts. Furthermore, copper sulfate, and manganese sulfate were previously taught to be included in a pet food composition, particularily if one desired to improve an animal's overall health. One would be motivated to include zinc sulfate and/or zinc chloride in the composition because zinc has been previously taught to treat skin disorders in dogs by the '182 prior art. Lastly, copper sulfate was disclosed by the '435 prior art as an ingredient in a pet food that improves an animal's overall health. Furthermore, the '182 prior art teaches that it is an inhibitor against zinc induced anemia, providing an additional motivation for its inclusion in the pet food composition

Instant claims 22, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,247,562 (hereinafter '562) by Bernotavicz , U.S. Application 2001/0002272 (hereinafter the '272) by Brunner, U.S. Patent

No. 2,859,115 (hereinafter the '115) by Rivoche, U.S. Patent No. 5,171,603 (hereinafter the '603) by Singer *et al*, The Merck Veterinary Manual 8th Edition as copyrighted in 1998, U.S. Patent No. 6,277,435 (hereinafter '435) by Lacombe *et al*. and U.S. Patent No. 3,422,182, (hereinafter '182) by Knapp *et al*, as applied to instant claim 16 -21 above, in further view of U.S. Patent No. 5,364,845 (hereinafter '845) by Henderson, ZA 9,905,557 (hereinafter '557) by Log-Negentien Beleggings (PTY) LTD, and U.S. Patent 5,919,499 (hereinafter '499) by Lawley.

Instant claim 22 recites the limitations of instant claim 21, which depends which depends from instant claim 20 which depends which depends from instant claim 19 which depends from instant claim 18 which depends from instant claim 17 which depends from instant claim 16, with the additional limitations that (a) when the composition comprises zinc, the composition comprises from about 0.001% to about 1% zinc ion, by weight of the composition; (b) when the composition comprises tin, the composition comprises from about 0.0005% to about 0.1% tin ion, by weight of the composition; (c) when the composition comprises copper, the composition comprises from about 0.0005% to about 0.1% copper ion, by weight of the composition; and (d) when the composition comprises manganese, the composition comprises from about 0.001% to about 0.5% manganese ion, by weight of the composition.

The limitations of instant claims 16-21 are discussed supra.

The Merck Veterinary Manual 8th Edition teaches the American Association of Feed Control (AAFCO) Nutrient Requirements for dogs. In particular, the minimum amount of manganese required in dog food is 0.0005% by weight, with no upper limit disclosed. The amount copper required in dog food ranges from 0.00073% to 0.025% by weight. The amount of zinc required is may range from 0.012% to 0.1% by weight (page 1626). The Merck Veterinary Manual 8th Edition also teaches that manipulation of dietary intake of minerals (with Ca, P Na, Mg, and Cu specifically recited), for therapeutic effect is common (page 1630; Minerals section).

However, the Merck Veterinary Manual 8th Edition does not teach an upper limit for manganese in the table, "AAFCO Nutrient Requirements for Dogs."

The '845 prior art, a therapeutic composition for repair of connective tissue in mammals, discloses that manganese further acts as a cofactor which, in combination with the sulfate (SO_4) , provides synergist effect in converting glucosamine into glycosaminoglycans (GAG's) neccessary for cartilage (Col. 3, lines 66-68; Col. 4; lines 1-2). Manganese ascorbate is preferred for the present invention, but other manganese salts such, as for example, sulfate or gluconate may be used but not preferred. (Col.4, lines 35-39). Manganese ascorbate is preferred because it is a soluble salt which also provides ascorbic acid needed for collagen synthesis (Col. 4, lines 35-36). The '845 prior art teaches administered capsules of the therapeutic composition (Cases 1-7; Col. 8 and 9).

However the '845 prior art does not disclose administering the therapeutic composition in food or a weight percent that the manganese salt should be present in, if administered with food.

The '449 prior art teaches adding supplements to a food and feeding the food to a dog (Col. 5, lines 34-42; Example 3, Col. 15)

The '557 prior art teaches a chemical treatment for arthritis (abstract). The composition contains 0.2 parts by weight manganese (page 5, lines 23 to end; page 6 lines 5-15).The composition was fed to 10 dogs (page 6, lines 20-26). The examiner notes that 10 g of the composition was fed daily (page 6, lines 20-26), resulting in administration of 0.2% of manganese per kg of the composition. The '557 prior art teaches that 200 mg of the composition per kilogram bodyweight provides relief (page 10, lines 20-25).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the amount of manganese ion disclosed to be in the gravy component of the dog food composition of the '562 prior art. One would have been motivated to do so because the Merck Veterinary Manual 8th Edition does not provide an upper limit for the amount of manganese present in dog food. The Merck Veterinary Manual 8th Edition also teaches that it is routine to modify the amount of minerals in an animals diet for therapeutic effect. One would have been further motivated to modify the amount of manganese ion present in the composition because the '845 prior art teaches that manganese further acts as a cofactor which, in combination with the sulfate (SO_4) , provides synergist effect in converting glucosamine into glycosaminoglycans (GAG's) neccessary for cartilage (Col. 3, lines 66-68; Col. 4; lines 1-2) in mammals such as dogs, and teaches use of water soluble forms of manganese (such as manganese sulfate or manganese ascorbate). One would have been additional motivated to adjust the amount of manganese ion present in the composition of

the '562 prior art to comprise 0.2% of the composition because the '557 prior art teaches used of 0.2% manganese by weight of the composition, provided that it provides approximately 200 mg of manganese per kg by weight of the dog. One would have been motivated to optimize the manganese ion in the composition of the dog food because the '499 prior art teaches that it is common to add supplements to dog food.

Instant claim 23 recites the limitations of instant claim 22, which depends from instant claim 21 which depends from instant claim 20 which depends which depends from instant claim 19 which depends from instant claim 18 which depends from instant claim 17 which depends from instant claim 16, with the additional limitation that the phosphate component comprises at least about 0.05 % by weight of the composition.

The limitations of instant claims 16-22 are discussed supra.

The '272 prior art teaches tetrasodium pyrophosphate in a concentration of 0.5% by weight of pet food (paragraph 23).

Instant claim 24 recites the limitations of instant claim 23, which depends from instant claim 22 which depends from instant claim 21 which depends from instant claim 20 which depends which depends from instant claim 19 which depends from instant claim 18 which depends from instant claim 17 which depends from instant claim 16, with the additional limitation that at least a portion of the phosphate component is a pyrophosphate.

The limitations of instant claims 16-23 are discussed supra.

The '272 prior art teaches tetrasodium pyrophosphate in a concentration of 0.5% by weight of pet food (paragraph 23).

Instant claim 25 recites the limitations of instant claim 23, which depends from instant claim 22 which depends from instant claim 21 which depends from instant claim 20 which depends which depends from instant claim 19 which depends from instant claim 18 which depends from instant claim 17 which depends from instant claim 16, with the additional limitation that wherein at least a portion of the phosphate component is a polyphosphate.

The limitations of instant claims 16-23 are discussed supra.

The '272 prior art teaches tetrasodium pyrophosphate (paragraph 23). The examiner notes that pyrophosphate is a polyphosphate.

Instant claims 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod and U.S. Patent 5,296,209 (hereinafter the '209) by Simone *et al.*

Instant claim 26 recites an edible composition, comprising: (a) an amount of a soluble mineral component comprising one or more minerals selected from the group consisting of zinc, manganese, tin, copper, and mixtures thereof, wherein the amount is an effective amount for use as an oral medicament, and wherein at least a portion of the mineral component is coated on the surface of

the edible composition; (b) a further amount of a phosphate component, wherein the further amount is an effective amount for use as an oral medicament; wherein the edible composition is a companion animal chew.

The '244 prior art teaches an animal chew toy (paragraph 1). One of objectives of the chew toy is to enrich the animals diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). The '224 specifically prefers inclusion of manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). It is evident that these minerals are in a soluble form, since it is taught that the additives (*i.e.* the minerals) are incorporated into a soaking solution and allowed to coat and or penetrate the molded chew toy. Preferably, a water solution containing the vitamins/minerals and/or herbs can be employed (paragraph 18). The '224 prior art also recognizes a need for inclusion of vitamin and mineral supplements (such as glucosamine) to ensure proper health and prevent malnutrition (paragraph 4). The '244 prior art teaches that phosphorus is present (paragraph 16).

However, the '224 prior art does not teach inclusion of a phosphate component in or on the chew for use as an oral medicament.

The '209 prior art teaches a chew that contains an inorganic pyrophosphate incorporated into a chew (Col. 4 lines 6-10). The inorganic pyrophosphate salts serve as a tartar control additives (Col. 4 lines 6-10).

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made, to include pyrophosphate salts in the

chew taught the '244 prior art in order to improve the chew taught by the '244 prior art. One would have been motivated to do so because the '244 prior art recognizes a need for inclusion of vitamin and mineral supplements to ensure proper health and prevent malnutrition and the '209 prior art teaches that inclusion of pyrophosphate salts in chews prevents tartar.

Instant claims 27 -30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod and U.S. Patent 5,296,209 (hereinafter the '209) by Simone *et al,* as applied in instant claim 26, in further view of and U.S. Patent No. 6,060,100 (hereinafter '100) by Koller.

Instant claim 27 recites the limitations of instant claim 26 with the additional limitations that the edible composition is substantially free of rawhide.

The limitations of instant claim 26 are addressed supra.

The '244 prior art teaches that collagen may be present with *either* casein, starch, vegetable matter, rawhide, peanut bits/flour, animal meal and/or any other thermoplastic resin (paragraph 8; italics by examiner for emphasis). The '244 prior art teaches inclusion of rawhide in a chew (paragraph 29) and chews that contain no rawhide (paragraph 28). The '224 prior art also recognizes a need for inclusion of vitamin and mineral supplements (such as glucosamine) to ensure proper health and prevent malnutrition (paragraph 4).

However, the '244 prior art does not provide a rationale as to why one chew (rawhide containing versus rawhide-free) would be preferable over the other.

The '100 prior art teaches that "rawhide is particularly bad for a dog's health as it is not digestible" (Col.1, lines 37-38). While, the '209 prior art additionally teaches that rawhide dog chews are expensive and that the indigestible leather fragments swallowed by the dogs frequently cause severe gastrointestinal blockage or diarrhea (Col. 1, lines 54-57)

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to make the rawhide-free chew as taught by the '244 prior art. One would have been motivated to do so because the '244 prior art expresses a desire to ensure the proper health of an animal and the '100 prior art teaches that rawhide is bad for a dog's health.

Instant claim 28 recites the limitations of instant claim 27, which depends from instant claim 26, with the additional limitation that the mineral component comprises at least two minerals selected from the group consisting of zinc, manganese, tin, copper and mixtures thereof.

The limitations of instant claims 26 and 27 are addressed supra.

The '224 teaches a preference for inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16).

Instant claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod, U.S. Patent 5,296,209 (hereinafter the '209) by Simone *et al,* and U.S. 6,060,100 (hereinafter '100) by Koller, as applied in instant claims 26-28 above, in further view of the Merck Veterinary Manual 8th Edition as copyrighted in 1998.

Instant claim 29 recites the limitations of instant claim 28, which depends from instant claim 27 which depends from instant claim 26, with the additional limitation that the edible composition comprises at least about 0.01% of the mineral component by weight of the composition.

The limitations of instant claims 26-28 are addressed supra.

The '224 teaches inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). The '244 prior art also teaches that one of its objectives is to enrich the animal's diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). The '244 prior art also teaches that one of the deficiencies of natural, organic, and vegetarian diets developed by owners is that many of the published recipes have not been properly balanced using nutrient averages as taught by The Merck Veterinary Manual 8th Edition (paragraph 4).

The '244 prior art does not teach any specific percentages for the minerals that are to be included in the taught chew.

The Merck Veterinary Manual 8th Edition teaches that the minimum nutrient requirement for dogs for zinc, manganese, and copper (all of which are included in the composition taught by the '244 prior art) is 0.012%, 0.0005%, and 0.00073% respectively by weight. The sum of these percentages is 0.013%, which is at least about 0.01% (page 1626).

Therefore, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to include at least about 0.01% minerals in the composition taught by the '244 prior art. One would have been motivated to do so because the '244 prior art teaches enriching the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6) and the proper minimum amount of zinc, manganese, and copper required to meet the nutrient requirement for a dog is within the disclosed range. Furthermore, recitation of a mineral component greater than 0.01% is simply optimization of a result effective variable within a range that was previously taught by the prior art.

Instant claim 30 recites the limitations of instant claim 29, which depends from instant claim 28 which depends from instant claim 27 which depends from instant claim 26, with the additional limitation that the composition comprises least about 0.01% of the mineral component by weight of the composition.

The limitations of instant claims 26-29 are addressed supra.

The '209 prior art teaches that the inorganic pyrophosphate is incorporated (i.e. integrated) into a chew (Col. 4 lines 6-10).

Instant claim 31 recites the limitations of instant claim 30, which depends from instant claim 29 which depends from instant claim 28 which depends from instant claim 27 which depends from instant claim 26, with the additional limitation that the edible composition comprises at least 0.02% of the mineral component by weight of the composition.

The limitations of instant claims 26-30 are addressed supra.

The '224 specifically prefers inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). The '244 prior art also teaches that one of its objectives is to enrich the animal's diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). The '244 prior art also teaches that one of the deficiencies of natural, organic, and vegetarian diets developed by owners is that many of the published recipes have not been properly balanced using nutrient averages as taught by The Merck Veterinary Manual 8th Edition (paragraph 4).

The '244 prior art does not teach any specific percentages for the minerals that are to be included in the taught chew.

The Merck Veterinary Manual 8th Edition teaches the American Association of Feed Control (AAFCO) Nutrient Requirements for dogs. In particular, the minimum amount of Manganese required in dog food is 5 mg/kg, (or 0.0005% by weight). The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight) while the maximum amount of copper permitted is 250 mg/kg (0.025% by weight). The minimum amount of zinc required is 0.012%. The maximum amount of zinc required is

0.1 %. Therefore the amount of the recited minerals can range from 0.01323-0.1255% (page 1626).

Therefore, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to optimize the amount of minerals in the chew taught by the '244 prior art. One would have been motivated to do so because the '244 prior art teaches enriching the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). One would have been further motivated to supply a mineral component at least 0.02% of the composition because the Merck Veterinary Manual 8th Edition teaches a range of amounts that are acceptable to meet a dog's nutrient requirements for zinc, copper, and manganese. The range for these three metals falls within the claim limitations, "of at least about 0.02%." Furthermore, recitation of a mineral component, "of at least about 0.02%" is simply optimization of a result effective variable within a range that was previously taught by the prior art.

Instant claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod, U.S. Patent No. 5,296,209 (hereinafter the '209) by Simone *et al,* U.S. Patent No. 6,060,100 (hereinafter '100) by Koller, and The Merck Veterinary Manual 8th Edition as copyrighted in 1998, as applied in instant claims 26-31 above, in further view of U.S. Patent No. 6,277,435 (hereinafter '435) by Lacombe *et al.* and U.S. Patent No. 3,422,182, (hereinafter '182) by Knapp *et al.*

Instant claim 32 recites the limitations of instant claim 31, which depends from instant claim 30 which depends the limitations of instant claim 29 which depends instant claim 28 which depends from instant claim 27 which depends from instant claim 26, that when the mineral component comprises zinc, manganese, zinc, tin or copper, the salt is selective from the respective Markush group.

The limitations of instant claims 26-31 are addressed supra.

The '244 prior art teaches that the minerals are incorporated in a soaking solution and that the minerals can penetrate the chew (paragraph 18), demonstrating that these are water-soluble mineral salts. The '224 specifically prefers inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16).

However, the '244 prior art does not disclose specific water soluble mineral salts.

The '435 prior art recites a pet food which can be served daily, with noticeable improvement in the animal's health" (Col.3, lines 1-3). This pet food contains the soluble mineral components copper sulfate, and manganese sulfate (Col.4, lines 3-10). The '182 prior art teaches administration of zinc in an animal's drinking water or food (Col 2. lines 41-50) to treat mange. Zinc sulfate and zinc chloride are disclosed as being water soluble zinc salts (Col. 2, lines 60-65) which can be administered by the '182 prior art.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include copper sulfate, manganese sulfate, and/or zinc sulfate and zinc chloride in the chew taught by the '244 prior art. One would have been motivated to do so because the '244 prior art expresses a desire to enrich the

chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Manganese, zinc, and copper are taught to be included among minerals to be included in the chew of the '244 prior art and may be added to the soaking solution. Copper sulfate, manganese sulfate, and/or zinc sulfate and zinc chloride are water soluble salts of these desired minerals, and are taught to be present in other pet foods (or as supplements that may be added to the pet food) by the '182 and '435 prior art.

Instant claim 33 recites the limitations of instant claim 32, which depends from instant claim 31 which depends from instant claim 30 which depends the limitations of instant claim 29 which depends instant claim 28 which depends from instant claim 27 which depends from instant claim 26, with the additional limitation that at least a portion of the phosphate component is a polyphosphate.

The limitations of instant claims 26-32 are addressed supra.

The '209 prior art teaches that the inorganic pyrophosphate is incorporated (i.e. integrated) into a chew (Col. 4 lines 6-10). Concentrations of pyrophosphate that are suitable are taught to be 0.5 to about 15% dry weight of the chew product (Col. 4, lines15-19). The examiner notes that a pyrophosphate is a polyphosphate.

Instant claim 34 recites the limitations of instant claim 32, which depends from instant claim 31 which depends from instant claim 30 which depends the limitations of instant claim 29 which depends instant claim 28 which depends from instant claim 27

which depends from instant claim 26, with the additional limitation that at least a portion of the phosphate is a pyrophosphate.

The limitations of instant claims 26-32 are addressed supra.

The '209 prior art teaches that the inorganic pyrophosphate is incorporated (i.e. integrated) into a chew (Col. 4 lines 6-10). Concentrations of pyrophosphate that are suitable are taught to be 0.5 to about 15% dry weight of the chew product (Col. 4, lines15-19).

Instant claim 35 recites the limitations of instant claim 32, which depends from instant claim 31 which depends from instant claim 30 which depends the limitations of instant claim 29 which depends instant claim 28 which depends from instant claim 27 which depends from instant claim 26, with the additional limitation that the edible composition comprises at least 0.05% of the phosphate component by weight of the composition.

The limitations of instant claims 26-32 are addressed supra.

The '209 prior art teaches that the inorganic pyrophosphate is incorporated (i.e. integrated) into a chew (Col. 4 lines 6-10). Concentrations of pyrophosphate that are suitable are taught to be 0.5 to about 15% dry weight of the chew product (Col. 4, lines15-19). This is at least about 0.05%.

Instant claim 36 recites the limitations of instant claim 35, which depends from instant claim 32 which depends from instant claim 31 which depends from instant claim 30 which depends from of instant claim 29 which depends from instant claim 28 which

depends from instant claim 27 which depends from instant claim 26, with the additional limitation that the edible composition comprises at least about 0.5% of the phosphate component.

The limitations of instant claims 26-32, and 35 are addressed supra.

The '209 prior art teaches that the inorganic pyrophosphate is incorporated (i.e. integrated) into a chew (Col. 4 lines 6-10). Concentrations of pyrophosphate that are suitable are taught to be 0.5 to about 15% dry weight of the chew product (Col. 4, lines15-19). This is at least about 0.5%.

Instant claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod, and U.S. Patent 5,011,679 (hereinafter the '679) by Spanier *et al*.

Instant claim 37 recites (a) an amount of a soluble mineral component comprising a mineral selected from the group consisting of zinc, manganese, tin, copper, and mixtures thereof, wherein the amount is an effective amount for use as an oral medicament; and

(b) a further amount of a phosphate component, wherein the further amount is an effective amount for use as an oral medicament, and wherein at least a portion of the phosphate component is coated on the surface of the edible composition; wherein the edible composition is a companion animal chew.

The '244 prior art teaches an animal chew toy (paragraph 1). One of objectives of the chew toy is to enrich the animals diet with vitamins/minerals and herbs to ensure that

the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). The '224 specifically prefers inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). It is evident that these minerals are in a soluble form, since it is taught that "the additives are incorporated into a soaking solution and allowed to coat and or penetrated the molded chew toy. Preferably a water solution containing the vitamins/minerals and/or herbs can be employed (paragraph 18). The '224 prior art also recognizes a need for inclusion of vitamin and mineral supplements (such as glucosamine) to ensure proper health and prevent malnutrition (paragraph 4). The '244 prior art teaches that phosphorus is present (paragraph 16).

However, the '224 prior art does not teach inclusion of a phosphate on the surface of the chew.

The '679 prior art teaches a rawhide chew containing a pyrophosphate coating (Abstract). The object of the chew is to prevent tartar accumulation on dog's teeth by the chewing and eating of raw hide having a coating containing pyrophosphate (Col. 8, lines 1-5). The '679 prior art teaches that prevention of calculus or tartar, the invention formulation is in effect an anti-cariogenic agent (Col.8, lines 34-41). It is preferred that the pyrophosphates are water soluble (Col. 11, lines 37-38). The '679 prior art teaches that the coating slurry (which contains the pyrophosphate) may be applied to the rawhide chew by any suitable means such as spraying or soaking (Col. 14, lines 1-3).

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made, to include a water-soluble pyrophosphate in the soaking solution taught by the '244 prior art to coat and penetrate the animal chew toy taught by the '244 prior art in order to improve the chew taught by the '244 prior art. One would

have been motivated to do so because the '244 prior art recognizes a need for inclusion of vitamin and mineral supplements to ensure proper health and prevent malnutrition and the '679 prior art teaches that pyrophosphate coatings on chews prevent tartar and cavities.

Instant claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod, and U.S. Patent No. 5,011,679 (hereinafter the '679) by Spanier *et al*, as applied to instant claim 37 above, in further view of U.S. Patent No. 6,060,100 (hereinafter '100) by Koller.

Instant claim 38 recites the limitations of instant claim 37 with the additional limitation that the composition is substantially free of rawhide.

The limitations of instant claim 37 are addressed supra.

The '244 prior art teaches that collagen may be present with *either* casein, starch, vegetable matter, rawhide, peanut bits/flour, animal meal and/or any other thermoplastic resin (paragraph 8; italics by examiner for emphasis). The '244 prior art teaches inclusion of rawhide in a chew (paragraph 29) and chews that contain no rawhide (paragraph 28). The '224 prior art also recognizes a need for inclusion of vitamin and mineral supplements (such as glucosamine) to ensure proper health and prevent malnutrition (paragraph 4).

However, the '244 prior art does not provide a rationale as to why one chew (rawhide containing versus rawhide-free) would be preferable over the other.

The '100 prior art teaches that "rawhide is particularly bad for a dog's health as it is not digestible" (Col.1, lines 37-38).

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to make the rawhide-free chew as taught by the '244 prior art. One would have been motivated to do so because the '244 prior art expresses a desire to ensure the proper health of an animal and the '100 prior art teaches that rawhide is bad for a dog's health.

Instant claims 39, 40, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod, and U.S. Patent No. 5,011,679 (hereinafter the '679) by Spanier *et al* and U.S. Patent No. 6,060,100 (hereinafter '100) by Koller, as applied to instant claims 37 and 38 above, in further view of the Merck Veterinary Manual 8th Edition as copyrighted in 1998.

Instant claim 39 recites the limitations of instant claim 39, which depends from instant claim 37, with the additional limitation that the edible composition comprises at least about 0.01% of the mineral component, by weight of the composition.

The limitations of instant claims 37 and 38 are addressed supra.

The '224 specifically prefers inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). The '244 prior art also teaches that one of its objectives is to enrich the animal's diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). The '244 prior art also teaches that one of the deficiencies of natural, organic, and vegetarian diets developed by owners is that many of the published recipes have not been properly balanced using nutrient averages as taught by The Merck Veterinary Manual 8th Edition (paragraph 4).

The '244 prior art does not teach any specific percentages for the minerals that are to be included in the taught chew.

The Merck Veterinary Manual 8th Edition teaches that the minimum nutrient requirement for dogs for zinc, manganese, and copper (all of which are included in the composition taught by the '244 prior art) is 0.012%, 0.0005%, and 0.00073% respectively by weight (page 1626). The sum of these percentages is 0.013%, which is at least about 0.01%.

Therefore, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to include at least about 0.01% minerals in the composition taught by the '244 prior art. One would have been motivated to do so because the '244 prior art teaches enriching the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6) and the proper minimum amount of zinc, manganese, and copper required to meet the nutrient requirement for a dog is within the disclosed range. Furthermore,

recitation of a mineral component greater than 0.01% is simply optimization of a result effective variable within a range that was previously taught by the prior art.

Instant claim 40 recites the limitations of instant claim 39, which depends from instant claim 38 which depends from instant claim 37, with the additional limitation that at least a portion of the mineral component is integrated within the edible composition.

The limitations of instant claims 37-39 are addressed supra.

The '244 prior art teaches that the additives (i.e. minerals) that are incorporated into a soaking solution and are allowed to coat and/or penetrate the chew (paragraph 18)

Instant claim 41 recites the limitations of instant claim 40, which depends from instant claim 39 which depends from instant claim 38 which depends from instant claim 37, with the additional limitation that at least a portion of the mineral component is coated on the surface of the edible composition.

The limitations of instant claims 37-40 are addressed supra.

The '244 prior art teaches that the additives (i.e. minerals) that are incorporated into a soaking solution and are allowed to coat and/or penetrate the chew (paragraph 18).

Instant claim 42 recites the limitations of instant claim 41, which depends from instant claim 40 which depends from instant claim 39 which depends from instant claim 38 which depends from instant claim 37, with the additional limitation that the edible composition comprises at least about 0.02% of the mineral component, by weight of the composition.

The limitations of instant claims 37-41 are addressed supra.

The '224 specifically prefers inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). The '244 prior art also teaches that one of its objectives is to enrich the animal's diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). The '244 prior art also teaches that one of the deficiencies of natural, organic, and vegetarian diets developed by owners is that many of the published recipes have not been properly balanced using nutrient averages as taught by The Merck Veterinary Manual 8th Edition (paragraph 4).

The '244 prior art does not teach any specific percentages for the minerals that are to be included in the taught chew.

The Merck Veterinary Manual 8th Edition teaches the American Association of Feed Control (AAFCO) Nutrient Requirements for dogs. In particular, the minimum amount of Manganese required in dog food is 5 mg/kg, (or 0.0005% by weight). The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight) while the maximum amount of copper permitted is 250 mg/kg (0.025% by weight). The minimum amount of zinc required is 0.012%. The maximum amount of zinc required is 0.1 % (page 1626).Therefore the amount of the recited minerals can range from 0.01323-0.1255% (page 1626),

Therefore, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to optimize the amount of minerals in the chew taught by the '244 prior art. One would have been motivated to do so because the '244 prior art teaches enriching the chew with vitamins, minerals and herbs to ensure that

the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). One would have been further motivated to supply a mineral component at least 0.02% of the composition because the Merck Veterinary Manual 8th Edition teaches a range of amounts that are acceptable to meet a dog's nutrient requirements for zinc, copper, and manganese. The range for these three metals falls within the claim limitations, "of at least about 0.02%." Furthermore, recitation of a mineral component, "of at least about 0.02%" is simply optimization of a result effective variable within a range that was previously taught by the prior art.

Instant claims 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod, and U.S. Patent No. 5,011,679 (hereinafter the '679) by Spanier *et al*, U.S. Patent No. 6,060,100 (hereinafter '100) by Koller and Merck Veterinary Manual 8th Edition as copyrighted in 1998, as applied to instant claims 37-42 above, in further view of U.S. Patent No. 6,277,435 (hereinafter '435) by Lacombe *et al.* and U.S. Patent No. 3,422,182, (hereinafter '182) by Knapp *et al.*

Instant claim 43 recites the limitations of instant claim 42, which depends from instant claim 41 which depends from instant claim 40 which depends from instant claim 39 which depends from instant claim 38 which depends from instant claim 37, with the additional limitation that when zinc tin copper or manganese are present they are selected from a respective Markush group.

The limitations of instant claims 37-42 are addressed supra.

The '244 prior art teaches that the minerals are incorporated in a soaking solution and that the minerals can penetrate the chew (paragraph 18), demonstrating that these are water-soluble mineral salts.

However, the '244 prior art does not disclose specific water soluble mineral salts.

The '435 prior art recites a pet food which can be served daily, with noticeable improvement in the animal's health" (Col.3, lines 1-3). This pet food contains the soluble mineral components copper sulfate, and manganese sulfate (Col.4, lines 3-10). The '182 prior art teaches administration of zinc in the animal's drinking water or food (Col 2. lines 41-50) to treat mange. Zinc sulfate and zinc chloride are disclosed as being water soluble zinc salts (Col. 2, lines 60-65) which can be administered.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include copper sulfate, manganese sulfate, and/or zinc sulfate and zinc chloride in the chew taught by the '244 prior art. One would have been motivated to do so because the '244 prior art expresses a desire to enrich the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Manganese, zinc, and copper are taught to be included among minerals to be included in the chew of the '244 prior art and may be added to the soaking solution. Copper sulfate, manganese sulfate, and/or zinc sulfate and zinc chloride are water soluble salts of these desired minerals, and are taught to be present in other pet foods (or as supplements that may be added to the pet food) by the '182 and '435 prior art.

Instant claim 44 recites the limitations of instant claim 43, which depends from instant claim 42 which depends from instant claim 41 which depends from instant claim 40 which depends from instant claim 39 which depends from instant claim 38 which depends from instant claim 37, with the additional limitation that at least a portion of the phosphate component is a polyphosphate.

The limitaitons of instant claims 37-43 are addressed supra.

The '679 prior art teaches a rawhide chew containing a pyrophosphate coating (Abstract). The examiner notes that pyrophosphate is a polyphosphate.

Instant claim 45 recites the limitations of instant claim 44, which depends from instant claim 43 which depends from instant claim 42 which depends from instant claim 41 which depends from instant claim 40 which depends from instant claim 39 which depends from instant claim 38 which depends from instant claim 37, with the additional limitation that at least a portion of the phosphate is a pyrophosphate.

The limitaitons of instant claims 37-44 are addressed supra.

The '679 prior art teaches a rawhide chew containing a pyrophosphate coating (Abstract). The examiner notes that pyrophosphate is a polyphosphate.

Instant claim 46 recites the limitations of instant claim 43, which depends from instant claim 42 which depends from instant claim 41 which depends from instant claim 40 which depends from instant claim 39 which depends from instant claim 38 which

depends from instant claim 37, with the additional limitation that the composition comprises that at least 0.05% of the phosphate component by weight.

The limitations of instant claims 37-43 are addressed supra.

The '679 prior art teaches a rawhide chew containing a pyrophosphate coating (Abstract). The '679 prior art teaches that the pyrophosphates are used in a sufficient amount to deliver (preferably) from 0.4 to 0.5 weight percent (based on the total composition) of pyrophosphate (Col. 12, lines 40-45).

Instant claim 47 recites the limitations of instant claim 46, which depends from instant claim 43 which depends from instant claim 42 which depends from instant claim 41 which depends from instant claim 40 which depends from instant claim 39 which depends from instant claim 38 which depends from instant claim 37, with the additional limitation that the composition comprises at least about 0.5% of the phosphate component by weight of the composition.

The limitations of instant claims 37-43, and 46 are addressed supra.

The '679 prior art teaches a rawhide chew containing a pyrophosphate coating (Abstract). The '679 prior art teaches that the pyrophosphates are used in a sufficient amount to deliver (preferably) from 0.4 to 0.5 weight percent (based on the total composition) of pyrophosphate (Col. 12, lines 40-45), which is at least about 0.5%.

Instant claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod, and U.S. Patent No. 5,011,679 (hereinafter the '679) by Spanier *et al*.

Instant claim 48 recites an edible composition comprising: (a) an amount of a soluble mineral component comprising a mineral selected from the group consisting of manganese, tin, copper, and mixtures thereof, wherein the amount is an effective amount for use as an oral medicament; (b) a further amount of a phosphate component, wherein the further amount is an effective amount for use as an oral medicament; wherein the edible composition is a companion animal chew

The '244 prior art teaches an animal chew toy (paragraph 1). One of objectives of the chew toy is to enrich the animals diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). The '224 specifically prefers inclusion of manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). It is evident that these minerals are in a soluble form, since it is taught that "the additives are incorporated into a soaking solution and allowed to coat and or penetrated the molded chew toy. Preferably a water solution containing the vitamins/minerals and/or herbs can be employed (paragraph 18). The '224 prior art also recognizes a need for inclusion of vitamin and mineral supplements (such as glucosamine) to ensure proper health and prevent malnutrition (paragraph 4). The '244 prior art teaches that phosphorus is present (paragraph 16).

However, the '224 prior art does not teach inclusion of a phosphate on the surface of the chew.

The '679 prior art teaches a rawhide chew containing a pyrophosphate coating (Abstract). The object of the chew is to prevent tartar accumulation on dog's teeth by the chewing and eating of raw hide having a coating containing pyrophosphate (Col. 8, lines 1-5). The '679 prior art teaches that prevention of calculus or tartar, the invention formulation is in effect an anti-cariogenic agent (Col.8, lines 34-41). It is preferred that the pyrophosphates are water soluble (Col. 11, lines 37-38). The '679 prior art teaches that the coating slurry (which contains the pyrophosphate) may be applied to the rawhide chew by any suitable means such as spraying or soaking (Col. 14, lines 1-3).

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made, to include a water-soluble pyrophosphate in the soaking solution taught by the '244 prior art to coat and penetrate the animal chew toy taught by the '244 prior art in order to improve the chew taught by the '244 prior art. One would have been motivated to do so because the '244 prior art recognizes a need for inclusion of vitamin and mineral supplements to ensure proper health and prevent malnutrition and the '679 prior art teaches that pyrophosphate coatings on chews prevent tartar and cavities.

Instant claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod, and U.S. Patent No. 5,011,679 (hereinafter the '679) by Spanier *et al*, as applied to instant claim 48 above, in further view of U.S. Patent No. 6,060,100 (hereinafter '100) by Koller.

Instant claim 49 recites the limitations of instant claim 48 with the additional limitation that the composition is substantially free of rawhide.

The limitations of instant claim 48 are addressed supra.

The '244 prior art teaches that collagen may be present with *either* casein, starch, vegetable matter, rawhide, peanut bits/flour, animal meal and/or any other thermoplastic resin (paragraph 8; italics by examiner for emphasis). The '244 prior art teaches inclusion of rawhide in a chew (paragraph 29) and chews that are rawhide-free (paragraph 28). The '224 prior art also recognizes a need for inclusion of vitamin and mineral supplements (such as glucosamine) to ensure proper health and prevent malnutrition (paragraph 4).

However, the '244 prior art does not provide a rationale as to why one chew (rawhide-containing versus rawhide-free) would be preferable over the other.

The '100 prior art teaches that "rawhide is particularly bad for a dog's health as it is not digestible" (Col.1, lines 37-38).

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to make the rawhide-free chew as taught by the '244 prior art. One would have been motivated to do so because the '244

prior art expresses a desire to ensure the proper health of an animal and the '100 prior art teaches that rawhide is bad for a dog's health.

Instant claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod, U.S. Patent No. 5,011,679 (hereinafter the '679) by Spanier *et al* and U.S. Patent No. 6,060,100 (hereinafter '100) by Koller, as applied to instant claims 48 and 49 above, in further view of The Merck Veterinary Manual 8th Edition as copyrighted in 1998.

Instant claim 50 recites the limitations of instant claim 49, which depends from instant claim instant claim 48, with the additional limitation that the composition comprises at least about 0.01% of the mineral component, by weight.

The limitations of instant claims 48 and 49 are addressed supra.

The '224 specifically prefers inclusion of manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). The '244 prior art also teaches that one of its objectives is to enrich the animal's diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). The '244 prior art also teaches that one of the deficiencies of natural, organic, and vegetarian diets developed by owners is that many of the published

recipes have not been properly balanced using nutrient averages as taught by The Merck Veterinary Manual 8th Edition (paragraph 4).

The '244 prior art does not teach any specific percentages for the minerals that are to be included in the taught chew.

The Merck Veterinary Manual 8th Edition teaches the American Association of Feed Control (AAFCO) Nutrient Requirements for dogs. In particular, the minimum amount of manganese required in dog food is 5 mg/kg, (or 0.0005% by weight), with no upper limit taught. The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight) while the maximum amount of copper permitted is 250 mg/kg (0.025% by weight; page 1626) . Therefore the amount of the minerals can range from 0.00123-0.0255% (page 1626), which is at least about 0.01%

Therefore, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to optimize the amount of minerals in the chew taught by the '244 prior art. One would have been motivated to do so because the '244 prior art teaches enriching the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). One would have been further motivated to supply a mineral component at least 0.01% of the composition because the Merck Veterinary Manual 8th Edition teaches a range of amounts that are acceptable to meet a dog's nutrient requirements for copper and manganese. The range for these two metals falls within the claim limitations, "of at least about 0.01%." Furthermore, recitation of a mineral component, "of at least about 0.01%" is simply optimization of a result effective variable within a range that was previously taught by the prior art.

Instant claims 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod, U.S. Patent No. 5,011,679 (hereinafter the '679) by Spanier *et al*, U.S. Patent No. 6,060,100 (hereinafter '100) by Koller, and The Merck Veterinary Manual 8th Edition as copyrighted in 1998, as applied to instant claims 48-50 above, in further view of U.S. Patent No. 6,277,435 (hereinafter '435) by Lacombe *et al.*

Instant claim 51 recites the limitations of instant claim 50, which depends from instant claim 49 which depends from instant claim 48, with the additional limitation that when tin, copper, or manganese are present, they are selected from a salt from their respective Markush group.

The limitations of instant claims 48-50 are addressed supra.

The '224 specifically prefers inclusion of manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). The '244 prior art also teaches that one of its objectives is to enrich the animal's diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). The '244 prior art teaches that the minerals are incorporated in a soaking solution and that the minerals can penetrate the chew (paragraph 18), demonstrating that these are water-soluble mineral salts.

However, the '244 prior art does not disclose specific water soluble mineral salts.

The '435 prior art recites a pet food which can be served daily, with noticeable improvement in the animal's health" (Col.3, lines 1-3). This pet food contains the soluble mineral components copper sulfate, and manganese sulfate (Col.4, lines 3-10).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include copper sulfate, manganese sulfate, and/or zinc sulfate and zinc chloride in the chew taught by the '244 prior art. One would have been motivated to do so because the '244 prior art expresses a desire to enrich the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Manganese and copper are taught to be included among minerals to be included in the chew of the '244 prior art and may be added to the soaking solution. Copper sulfate and manganese sulfate are water soluble salts of these recited minerals and are taught to be to be edible and desirable in pet foods by '435 prior art.

Instant claim 52 recites the limitations of instant claim 51, which depends from instant claim 50 which depends from instant claim 49 which depends from instant claim 48, with the additional limitation that the phosphate component is a polyphosphate.

The limitations of instant claims 48-51 are addressed supra.

The '679 prior art teaches a rawhide chew containing a pyrophosphate coating (Abstract). The '679 prior art teaches that the pyrophosphates are used in a sufficient amount to deliver (preferably) from 0.4 to 0.5 weight percent (based on the total composition) of pyrophosphate (Col. 12, lines 40-45).

Instant claim 53 recites the limitations of instant claim 51, which depends from instant claim 50 which depends from instant claim 49 which depends from instant claim 48, with the additional limitation that at least a portion of the phosphate component is a pyrophosphate.

The limitations of instant claims 48-51 are addressed supra.

The '679 prior art teaches a rawhide chew containing a pyrophosphate coating (Abstract). The '679 prior art teaches that the pyrophosphates are used in a sufficient amount to deliver (preferably) from 0.4 to 0.5 weight percent (based on the total composition) of pyrophosphate (Col. 12, lines 40-45).

Instant claim 54 recites the limitations of instant claim 51, which depends from instant claim 50 which depends from instant claim 49 which depends from instant claim 48, with the additional limitation that the composition comprises at least about 0.5% of the phosphate component and at least about 0.02% of the mineral component by weight of the composition.

The limitations of instant claims 48-51 are addressed supra.

The '679 prior art teaches a rawhide chew containing a pyrophosphate coating (Abstract). The '679 prior art teaches that the pyrophosphates are used in a sufficient amount to deliver (preferably) from 0.4 to 0.5 weight percent (based on the total composition) of pyrophosphate (Col. 12, lines 40-45), which is at least about 0.5%. As discussed above, the Merck Veterinary Manual 8th Edition teaches the American Association of Feed Control (AAFCO) Nutrient Requirements for dogs (page 1626). In particular, the minimum amount of manganese required in dog food is 5 mg/kg, (or

0.0005% by weight), with no upper limit taught. The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight) while the maximum amount of copper permitted is 250 mg/kg (0.025% by weight). Therefore the amount of the minerals can range from 0.00123-0.0255% (page 1626), which is at least about 0.02% mineral component by weight of the composition.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORI K. MATTISON whose telephone number is (571) 270-5866. The examiner can normally be reached on 9 am- 5 pm EST (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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